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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,439	09/11/2003	Takashi Okuda	242622US0X	4092
22850	7590	09/09/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			ZEMAN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/659,439	Applicant(s) OKUDA ET AL.	
	Examiner Robert A. Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-14 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 7-12 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and response filed on 6-10-2004 are acknowledged. Claims 1-2, and 4 have been amended. Claim 3 has been cancelled. Claims 5-14 have been added.

Newly submitted claims 13-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the inventions of claims 13 and 14 are each related to the invention of claims 1-2 and 4-12 as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the invention of claim 14 is a product of nature and the invention of claim 13 can be made by simple desiccation methods.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-14 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Consequently, claims 1-2 and 4-12 are currently under examination.

Priority

The certified translation of the priority document filed on 6-29-2004 is acknowledged. Applicant's claim for foreign priority based on an application filed in Japan on March 17, 2003 has been perfected.

Objections Withdrawn

The objection to the disclosure for inappropriate abbreviations is withdrawn in light of the amendment thereto.

The objection to claim 3 for an inappropriate abbreviation is withdrawn. Cancellation of said claim has rendered the objection moot.

The objection to claim 4 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of the amendment thereto.

New Claim Objections

Claim 9 is objected to because of the following informalities: said claim contains an obvious typographical error. "Dessicator" should read "desiccator". Appropriate correction is required.

Claim Rejections Withdrawn

35 USC § 112

The rejections of claims 1-4 under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims is withdrawn in lieu of the rejection detailed below.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the recitation of “evaporating distilled water in the drying container” is withdrawn in light of the amendment thereto.

The rejection of claims 2-4 under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Watanabe, M. *et al.* Nov. 2002. (J. Exp. Bio. 205: 2799-2802) is withdrawn. A new art rejection is outlined below.

New Grounds of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 and 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for a method of dry-preserving larval tissues of *Polypedium vanderplanki* by submerging the tissues in an insect fluid medium treated with heat and drying, does not reasonably provide enablement of a method for dry-preserving a tissue of non-larval tissue from *Polypedium vanderplanki*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims encompass a method for dry-preserving a tissue of a multicellular organism comprising placing a drying container containing a larva of a multicellular organism in a desiccator (humidity < 5% and evaporating distilled water in drying container of 220-230 µl per 24hr), wherein the multicellular organism is *Polypedium vanderplanki*. The claims further

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encompass a method for dry preserving a tissue of a *Polypedium vanderplanki*, comprising submerging the tissue of the *Polypedium vanderplanki* in an insect fluid medium treated with heat and drying for at least 48 hours.

The teachings of the specification are limited to the breeding of *P. vanderplanki* and dry-preserving the larval forms of *P. vanderplanki* by placing a group of ten larvae in a drying container containing distilled water and filter paper and placing in a desiccator (humidity < 5% and evaporating distilled water in drying container of 220-230 μ l/24hr). The teachings of the specification are silent regarding working examples of any tissues other than larval tissue in a method for dry-preserving tissues. The specification is also silent regarding any limitations of tissue size relating to the infusion of insect body fluid medium in the instant dry-preserving method. The specification is also silent to how other environmental factors are regulated, *e.g.* oxygen content during initial drying of *Polypedium vanderplanki* and/or the presence of free radicals that could inherently affect dry-preserving conditions, as well as storage factors upon dry-preserving with different tissues of *Polypedium vanderplanki*. Further, the specification is silent as to whether other tissues produce substances (*e.g.* trehalose) in response to lack of water and/or oxygen. The specification is equally silent on whether *Polypedium vanderplanki* tissues (other than larval tissues) contain cells which have inducible expression of trehalose that appear to be important in the dry preserving of tissues.

As outlined previously, Gordon, S.L. *et al.* September 2001 (Cryobiology 43(2): 182-187) teach preliminary findings of human mesenchymal stem cells (hMSCs) dry-preserved using trehalose compared to controls that do not recover in the absence of trehalose (see Materials and Methods, page 183). Gordon, S.L. *et al.* further disclose that trehalose has broad potential uses in

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tissue engineering and regeneration indicative of differentiation potential for fat and bone (see abstract). Gordon, S.L. *et al.* conclude that although preliminary findings are encouraging, research addressing consistency and duration of storage by considering factors such as cell water content, oxygen concentration, and the presence of free radicals still need to be addressed (see Discussion, pages 186-187).

Moreover, Watanabe *et al.* (J. Exper. Bio. September 2002, Vol. 205 pages 2799-2802) teach the underlying molecular and metabolic mechanisms of cryptobiosis largely remain a mystery (see Introduction, paragraph 2). Watanabe, M. *et al.* further teach rapid accumulation of trehalose plays a key role in the successful induction of cryptobiosis in *P. vanderplanki* (see Table 1). Watanabe, M. *et al.* suggest further investigations are needed to elucidate the mechanism(s) of the successful induction and recovery of cryptobiosis in the “higher” invertebrate *P. vanderplanki* and might be of enormous consequence for the field of cell and organ storage (see page 2801 at Table 1 and Discussion, paragraph 4). Applicants have not demonstrated any tissues (other than *P. vanderplanki* larva) that can undergo the rapid accumulation of trehalose that appears key to a successful induction of cryptobiosis.

In view of the state of the prior art set forth supra and/or full scope of Applicant's claimed invention; it would require undue experimentation by one of ordinary skill in the art to practice the claimed invention in *Polypedium vanderplanki* tissues other than larval tissue. Due to the level of predictability, without working examples and further direction provided by the inventor demonstrating dry-preserving of other *Polypedium vanderplanki* tissues, one of ordinary skill in the art would be unable to apply a method of dry-preserving of *P. vanderplanki* larval

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tissue directly to other *Polypedium vanderplanki* tissue. Applicants have not presented sufficient evidence to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 2 is rejected under 35 U.S.C. 102(a) as anticipated by Watanabe, M. *et al.* Nov. 2002. (J. Exp. Bio. 205: 2799-2802).

The claims are drawn to a method for dry-preserving a larva of a multicellular organism in a desiccator (humidity < 5% and evaporation rate of 220 to 230 $\mu\text{l}/24\text{hr}$), wherein the multicellular organism is *Polypedium vanderplanki*.

Watanabe, *et al.* teach a method for dry-preserving larva (*i.e.* larva contain tissues) of *P. vanderplanki* using a desiccator (<5% relative humidity) and drying over a period of 48h (0.22-0.23 ml/dy^{-1} (*i.e.* 220 to 230 $\mu\text{l}/24\text{hr}$) in Material and Methods, Desiccating Procedure page 2799.

Thus, Watanabe, *et al.* anticipates the instantly claimed invention.

It should be noted that in his response Applicant has stated that the aforementioned reference would not be available as prior art under 35 U.S.C. 102(a) once priority had been perfected. Contrary to Applicant's assertion, since the reference by Watanabe *et al.* was publicly available on September 12, 2002 and said reference was done by "others" (*i.e.* authorship is

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differs from the inventive entity of the instant application), said reference is a viable prior art reference under 35 U.S.C. 102 (a).

Conclusion

No claim is allowed.

Claims 5 and 6 are objected to as being dependent on a rejected claim.

Claims 1 and 4-12 are free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Robert A. Zeman". The signature is fluid and cursive, with the first name "Robert" and last name "Zeman" clearly distinguishable.

Robert A. Zeman
August 31, 2004